

EUROPEAN AND MEDITERRANEAN PLANT PROTECTION ORGANIZATION
ORGANISATION EUROPEENNE ET MEDITERRANEENNE POUR LA PROTECTION DES PLANTES
(11-17239)

Summary sheet of validation data for a diagnostic test

The EPPO Standard PM 7/98 *Specific requirements for laboratories preparing accreditation for a plant pest diagnostic activity* describes how validation should be conducted. It also includes definitions of performance criteria.

Target Organism	Curtobacterium flaccumfaciens pv flaccumfaciens	
Short description	Identification of Curtobacterium flaccumfaciens pv flaccumfaciens by conventional PCR	
Laboratory contact details	National Reference Centre, National Plant Protection Organization P.O. Box 9102, 6700 HC Wageningen, Netherlands	
Date and reference of the validation report	2011-06-24 - 2011 Validation report PCR for identification of Curtobacterium flaccumfaciens pv flaccumfaciens	
Validation process according to EPPO Standard PM 7/98:	Yes	
Reference of the test description	N/R	
Is the test the same as described in the EPPO DP?	Yes	
Is the lab accredited for this test?	No	
Plant species tested (if relevant)		
Matrices tested (if relevant)		
List of methods used		
Method for extraction / isolation / baiting of target organism from matrix		
Molecular methods, e.g. hybridization, PCR and real time PCR	X	conventional PCR
Serological methods: IF, ELISA, Direct Tissue Blot Immuno Assay		
Plating methods: selective isolation		
Bioassay methods: selective enrichment in host plants, baiting, plant test and grafting.		
Pathogenicity test		
Fingerprint methods: protein profiling, fatty acid profiling & DNA profiling		

Morphological and morphometrical methods intended for identification		
Biochemical methods: e.g. enzyme electrophoresis, protein profiling		
Other		
<u>Analytical sensitivity (= limit of detection)</u>		
What is smallest amount of target that can be detected reliably?	2,3 x 10 ⁷ cfu/ml.	
<u>Diagnostic sensitivity</u>		
Proportion of infected/infested samples tested positive compared to results from the standard test , see appendix 2 of PM 7/98	100%	
Specify the standard test	IF in combination with Fatty Acid Analysis	
<u>Analytical specificity</u>		
Specificity value	100%	
Number of strains/populations of target organisms tested	11 strains of Curtobacterium flaccumfaciens pv flaccumfaciens	
Number of non-target organisms tested	20 strains of non-target organisms	
Cross reacts with (specify the species)	none	
<u>Diagnostic Specificity</u>		
Proportion of uninfected/uninfested samples (true negatives) testing negative compared to results from a standard test	100%	
Specify the standard test	IF in combination with Fatty Acid Analysis	
<u>Reproducibility</u>		
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	100%	
<u>Repeatability</u>		
Provide the calculated % of agreement for a given level of the pest (see PM 7/98)	100%	
<u>Test performance study</u>		
Test performance study?	No	
Include brief details of the test performance study and its output.It available, provide a link to published article/report		
<u>Other information</u>		
Any other information considered	For the robustness: the DNA isolation methodology was tested	

useful e.g. robustness, ease of performing the test, etc.	in order to investigate whether this could have any influence on the outcome of the test. Both the QuickPick Plant DNA Kit (Bio-Nobile) on the Kingfisher and the High Pure PCR template preparation kit (Roche) performed equally well.
The following complementary files are available online:	<ul style="list-style-type: none">• 2011 Validation report PCR for identification of Cff